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For the President of the European Patent Office  
Le Président de l'Office européen des brevets  
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Patentanmeldung Nr.  
Patent application no.  
Demande de brevet n°

PCT/EP 98/03892

Blatt 2 der Bescheinigung  
Sheet 2 of the certificate  
Page 2 de l'attestation



Anmeldung Nr.: PCT/EP 98/03892  
Application no.:  
Demande n°:

Anmelder: 1. C.R. Bard, Inc. - Murray Hill, NJ; USA  
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Demandeur(s):

Bezeichnung der Erfindung:  
Title of the invention: Medical device with elastomeric bulb  
Titre de l'invention:

Anmeldetag: 25 June 1998 (25.06.98)  
Date of filing:  
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MEDICAL DEVICE WITH ELASTOMERIC BULBTECHNICAL FIELD

A pre-filled Foley catheter can be regarded as one example of a medical device with a proximal end and a distal end, an elastomeric bulb at the proximal end for storing fluid under pressure and a fluid acceptor at the distal end and a lumen connecting the bulb and the acceptor for flow of fluid from the bulb to the acceptor when the device is used, and including a control device at the proximal end of the lumen to prevent said fluid flow until said flow is desired. It is in this class of medical devices that the present invention is to be found.

BACKGROUND ART

The Foley catheter is a catheter device made out of elastomeric material, which is for urine drainage and which is installed with its distal end in the bladder of the patient. When the distal end reaches the bladder, sterile water is caused to flow along a lumen from the proximal to the distal end of the catheter, there to fill a balloon surrounding the lumen and defined by the elastomeric wall of the catheter. This balloon retains the distal end of the catheter in the bladder and allows a second lumen in the catheter shaft, open to the bladder at the distal end of the shaft, to drain urine from the bladder to the proximal end of the catheter.

In a so-called pre-filled Foley catheter, the device comes complete with a reservoir of sterile water in the proximal end of the device, and a clip over the shaft of the catheter

at its proximal end, which clip prevents the sterile water from flowing from the distended reservoir bulb along the lumen to the distal end of the catheter. The person placing the catheter is required to hold the catheter in the desired disposition relative to the body of the patient, and then remove the clip and squeeze the reservoir bulb, in order to inflate the balloon.

Achievement of a satisfactory shelf-life for pre-filled Foley catheters has proved to be a challenge. Common elastomeric material, such as Latex, is not entirely impermeable to the passage of water. Accordingly, the water in the distended bulb reservoir of elastomeric material can escape through the wall, given enough time. In order to achieve a satisfactory shelf-life (18 to 24 months) it has been proposed to cover the outside of the reservoir bulb with a coating of material more resistant to passage of water than latex. Nevertheless, residual problems remain.

One such problem is that the coating tends to crack, and this reduces the resistance to escape of water. Another problem is to achieve satisfactory continuity of the coating around the clip at the distal end of the bulb, and the customary filler valve at the proximal end of the bulb. Even then, there is potential for water to escape from the bulb by flowing lengthways along the elastomeric material of the wall of the bulb, until it has passed the distal and proximal ends of the waterproof coating material.

#### SUMMARY OF THE INVENTION

An object of the present invention is to achieve greater certainty, during the manufacture of pre-filled Foley catheters, that the catheter will deliver a satisfactory shelf life.

Thus, in accordance with the present invention, there is provided a medical device of the type identified above, and which is characterised in that said control device comprises a plug which blocks the lumen at its proximal end and includes a portion which extends proximally into the interior of the bulb, the plug being susceptible of manual manipulation, through the elastomeric material of the bulb, to unblock the lumen and permit the required fluid flow in the distal direction.

By resorting to a plug instead of an external clip, a number of unforeseen advantages emerge.

In particular, the stress distribution in the wall of the bulb at the neck at its distal end is much more uniform with a plug than with the customary clip. An enhanced ability to predict patterns of stress and strain at the balloon neck should in turn allow better waterproofing in the distal neck region.

Stabilisation of the interface between the bulb wall and the surfaces of the control device makes it easier to render the bulb fluid-tight in this interface zone. The medical device is much easier to pack and to handle in the terminal stages of manufacture because it lacks the bulk of an external clip. This external clip becomes separated from the conventional pre-filled Foley catheter, once the catheter has been installed, and one then has the task of disposing of the loose clip. With the device of the invention, the component parts of the control device are retained within the bulb. One handed operation of the valve requires less manual dexterity than with an external clip which has to be removed.

Prior to the making of this invention, applicant experimented with waterproof coatings on the inside of the elastomeric bulb. These attempts were abandoned because it

was found that the material of the coating tended to block the lumen at the distal end of the bulb. However, with the present invention, there is fresh potential for waterproofing the inside of the bulb, because the placement of the plug in the distal neck of the bulb, before any waterproof coating is introduced onto the inside surface of the bulb wall, will prevent the coating material from blocking the lumen at the distal end of the bulb. With appropriate design of the plug, a coating of waterproof material on the external surface of the plug ought not to have any adverse effect on the operation of the control device.

In another embodiment, it is envisaged that the plug device might carry with it a skirt of waterproof material, to serve as the waterproof wall of the bulb, or an inner waterproof surface coating of the wall of the bulb, the skirt being gathered at the proximal end of the bulb, and fitted around the customary bulb filler valve. Cakes are decorated using an icing sugar mixture which is extruded through an icing nozzle, itself set in the neck of an icing bag. The contemplated arrangement of plug and skirt might resemble an arrangement of icing nozzle and icing bag.

The control of flow of fluid in a lumen, using a plug which exhibits an annulus and a stem, the stem being separated from the annulus in order to allow fluid flow, is not in itself new. Such an arrangement is disclosed in, for example, GB-A-1573482 and US-A-4007738 published February 15, 1977. It is to be noted, however, that the proposal of the present invention is to place the control device such that it extends proximally into the interior of the bulb. This provides plenty of room for displacement of one part of the control device relative to the other, and for eliminating elastic stresses in a lumen wall which might otherwise act to bring the two displaced parts of the control device back into their original sealing disposition

relative to each other. It is by locating the control device partly within the bulb that many of the attractive technical effects of the present invention are released.

#### BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention, and to show more clearly how the same made be carried into effect, reference will now be made, to the accompanying drawings, in which:

Figure 1 is a longitudinal diametral section through a Foley catheter in accordance with the present invention; and

Figure 2 is a longitudinal diametral section through a control device of the Figure 1 catheter.

#### DESCRIPTION OF THE PREFERRED EMBODIMENT

Figure 1 shows a pre-filled Foley catheter which is conventional in all respects except for the control device at the distal end of the reservoir bulb. The catheter 10 comprises a shaft 11 of latex rubber which defines a balloon inflation lumen 12 and a drainage lumen 13. The drainage lumen 13 extends from a distal drainage port 14 to a drainage bag coupling element 15 at the proximal end of the catheter. The inflation lumen 12 connects a chamber 20 at the distal end of the catheter, but proximal of the drainage port 14, with a reservoir bulb 21 at the proximal end of the device. In Figure 1, both of the balloon 20 and bulb 21 are shown inflated, for the sake of clarity, but those skilled in the art will appreciate that the sterile water within the bulb 21 is not sufficient simultaneously to fill both the bulb and the balloon. The reality is that, when the bulb 21 is full, the balloon 20 is not yet inflated and, when the balloon 20 is fully inflated, the bulb 21 is deflated.



The bulb 21 has a proximal end 22 and a distal end 23. At the proximal end 22 is a filler valve 24, no different from the conventional one-way filler valve with which those skilled in the art will already be familiar. However, at the distal neck 23 of the bulb 21, there is not the conventional external clip to clamp together the walls of the lumen 12 but, rather, a plug 25 which is a friction fit inside the lumen 12, the plug 25 being introduced distally into the lumen 12 through the interior of the bulb 21 and, in so doing, elastically deforming the material of the shaft 11 of the catheter 10. Figure 2 shows in more detail the construction of this control device.

In Figure 2 the control device 25 can be seen to be made up of a frusto-conical plug portion 26 and a solid stem portion 27 which occludes the proximal end 28 of a bore 29 which extends completely through the plug portion 26, as far as its distal end 30. The solid stem 27 is integral with the plug portion 26, but joined to it by a narrow and weak circle 31 of material around the proximal end 28 of the bore 29.

The device 25 is formed from synthetic polymeric material which is selected so that manual manipulation of the solid stem 27 relative to the plug portion 26 is quite sufficient to tear the polymer material at a point on the circumference of the weak circle 31, thereby allowing the stem 27 to rotate relative to the plug portion 26, with further tearing of the material around the circle 31 putting in fluid communication the bulb 21 surrounding the stem 27 with the bore 29 through the length of the plug portion 26.

Because of the softness of the bulb, and the open space between the wall surfaces of the bulb 21 surrounding the stem 27, there is great scope for manual manipulation of the bulb, from outside it, to achieve a large angle of rotation

of the stem 27 relative to the plug portion 26, with consequent great certainty of putting the bulb 21 in communication with the bore 29.

Those skilled in the art will be familiar with the conventional dimensions of a pre-filled Foley catheter. Of course, many of these are determined by the dimensions of the associated parts of the human body. The researches of the present applicant, as to what are the preferred dimensions of the plug control device, have resulted in a proposal that the control device should be constructed in accordance with the following scheme of dimensions (all in mm): the stem portion 27 has a length of 10 and a diameter of 2.25; the plug portion has a length of 9 and a bore diameter of 2; the frusto-conical outer diameter range is from 5.5. to 4.3; there is a transition zone from the proximal end of the 2 mm axial bore of the plug portion, to the 2.25 mm diameter circle on the proximal end face of the plug portion, which extends distally from the proximal end face over a distance of 0.625 mm.

The bulb is water-proofed by dipping in Saran. Otherwise it could be water-proofed by, e.g. dipping or spraying it with silicone, neoprene rubber, butyl rubber or hydrophobic polyurethane.

One suitable polymer material for the plug device is polyvinylchloride. However, there is currently prejudice against the use of PVC. High impact polystyrene is another possibility. A polyester material such as polybutyleneterephthalate may be worthy of consideration. Styreneacrylonitrile is another polymer of particular interest. The selection of polymers for medical applications is a field in which there is considerable experience. Some special factors apply, for example, gamma ray sterilisation is usual, and the polymer must obviously be able to withstand all production process steps, including

sterilisation, as well as being stable enough to survive the required shelf life period in the environment in which it finds itself. Resistance to solvents, possibly acetone, may be another significant factor. Putting the bulb interior in communication with the tube should not result in any loose fragments of the control device, especially not any transport of such fragments to the fluid acceptor. Accordingly, the preferred failure mode between stem portion 27 and plug portion 26 is tearing.

Although the presently preferred embodiment involves a circle of weakness, and parting of the polymer material around the weakness circle 31, nevertheless it is contemplated that alternative embodiments, not presently preferred, might in the end prove more attractive, in which, for example, the stem portion 27 is not integral with the plug portion 26 but, rather, is a separate piece which is friction fitted with the proximal end 28 of the bore 29. If this were the case, then it might be appropriate to provide stepped or tapered portions of the proximal end of the bore 29 or the distal end of the stem 27.

Although the present invention arose out of a consideration of how to improve a specific product, the pre-filled Foley catheter, nevertheless the concept of the invention might be applicable elsewhere. In particular, the interaction of a plug stopper and a distended elastomeric reservoir of sterile fluid could be useful whenever there is need for a supply of sterile fluid from a bulb. Thus, it could be arranged that, while the plug remains intact, the fluid is safe and sterile within the bulb, and resistant to damage or decay but, upon a simple manipulation of the stem of the plug, a supply of sterile fluid is available, from the bulb, in whatever quantities and rate of flow are selected by the user, by varying the squeezing and manipulation of the elastomeric bulb.

CLAIMS

1. A medical device (10) with a proximal end (22) and a distal end (23), an elastomeric bulb (21) at the proximal end for storing fluid under pressure, a fluid acceptor (20) at the distal end and a lumen (12) connecting the bulb and the acceptor for flow of fluid from the bulb to the acceptor when the device is used, and including a control device (25) at the proximal end of the lumen to prevent said flow until said flow is desired  
characterised in that  
said control device (25) comprises a plug (26) which blocks the lumen at its proximal end and includes a portion (27) which extends proximally into the interior of the bulb (21), the plug being susceptible of manual manipulation, through the elastomeric material of the bulb, to permit the required fluid flow in the distal direction.
2. Device as claimed in claim 1 wherein the acceptor is a balloon (20).
3. Device as claimed in claim 1 or 2 wherein the bulb (21) is made of elastomer.
4. Device as claimed in claim 3 wherein the bulb (21) is made of latex rubber.
5. Device as claimed in any one of the preceding claims wherein the fluid is a liquid.
6. Device as claimed in claim 5 wherein the fluid is water.

7. Device as claimed in any one of the preceding claims wherein the bulb (21) is coated with a substance to inhibit the passage of the fluid through the wall thickness of the bulb.
8. Device as claimed in claim 7 wherein the coating is on the outside of the bulb wall thickness.
9. Device as claimed in any one of the preceding claims wherein the coating is on the inside surface of the bulb wall.
10. Device as claimed in any one of the preceding claims wherein the plug comprises an annulus of material with a proximal end face (30) and a distal end face (28) and a bore (29) extending between the two end faces.
11. Device as claimed in claim 10 and including a stem (27) extending proximal of the proximal end face (30) of the annulus coaxially with the bore.
12. Device as claimed in claim 11 wherein the stem is friction fitted within the bore.
13. Device as claimed in claim 11 wherein the stem is integral with the annular plug and joined to it by a circle of weakness (31).
14. Device as claimed in claim 13 wherein the plug is formed as only one piece of molded polymer material.
15. Device as claimed in any one of the preceding claims wherein the plug carries a fluid-tight skirt membrane which extends proximally from the proximal end face of the plug.

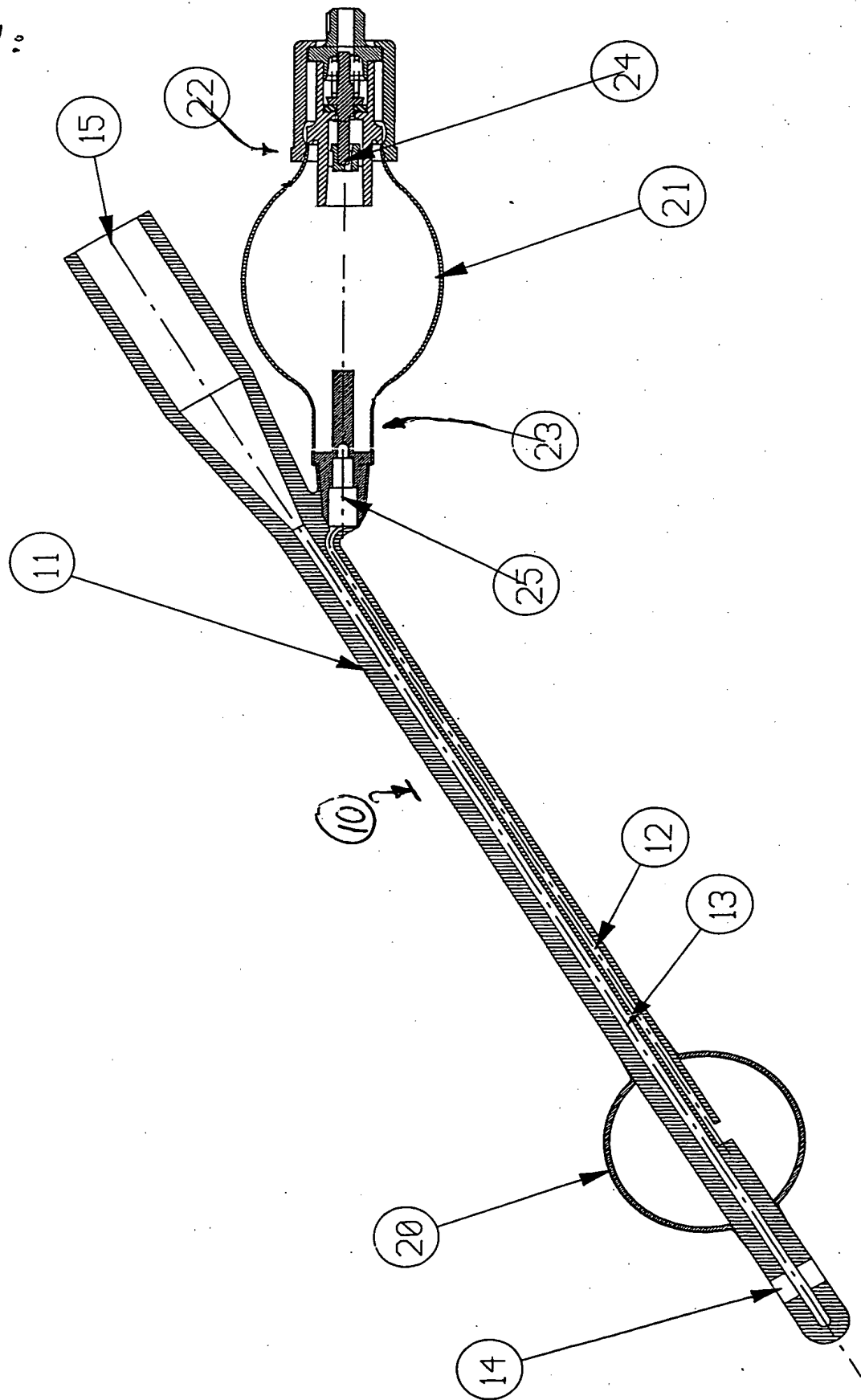
16. Device as claimed in any one of the preceding claims wherein the bulb (21) has an open proximal end (22) to receive the plug, the open proximal end being itself closed by a filler valve (24).
17. Device as claimed in any one of the preceding claims wherein the medical device is a catheter (10).
18. Device as claimed in claim 17 wherein the catheter is fashioned from latex rubber.
19. Device as claimed in claim 17 or 18 wherein the catheter is a drainage catheter.
20. Device as claimed in claim 19 when the catheter is a urinary catheter.
21. Device as claimed in claim 20 wherein the catheter is a Foley catheter.

ABSTRACT

In order to achieve greater certainty, during the manufacture of pre-filled Foley catheters, that the catheter will deliver a satisfactory shelf life there is provided, in accordance with the present invention, a medical device (10) with a proximal end (22) and a distal end (23), an elastomeric bulb (21) at the proximal end for storing fluid under pressure, a fluid acceptor (20) at the distal end and a lumen (12) connecting the bulb and the acceptor for flow of fluid from the bulb to the acceptor when the device is used, and including a control device (25) at the proximal end of the lumen to prevent said flow until said flow is desired, and which is characterised in that said control device (25) comprises a plug (26) which blocks the lumen at its proximal end and includes a portion (27) which extends proximally into the interior of the bulb (21), the plug being susceptible of manual manipulation, through the elastomeric material of the bulb, to permit the required fluid flow in the distal direction.

(Fig. 1)

FIG. 1:





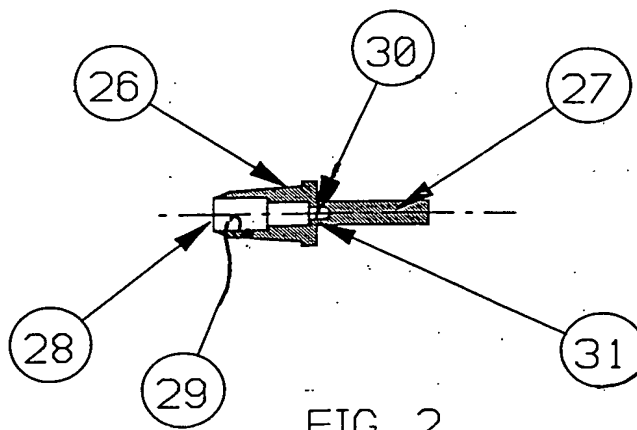


FIG. 2

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